

CLAIMS

What is claimed is:

1. Pharmaceutical dosage form comprising a central core including a pharmaceutical agent in a controlled-release composition, said core having two exposed opposite end surfaces and a peripheral surface at an outer edge of said core extending between said two opposed end surfaces, said peripheral edge surrounded by a diffusion-limiting sleeve, wherein said sleeve limits the diffusion of fluids into said core.
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2. Pharmaceutical dosage form, as recited in Claim 1, wherein said core and said sleeve are cylindrical and said opposite surfaces are circular.
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3. Pharmaceutical dosage form, as recited in Claim 2, wherein the length of said sleeve is less than the diameter of said sleeve.
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4. Pharmaceutical dosage form, as recited in Claim 1, wherein said pharmaceutical agent comprises an agent selected from troglitazone, rosiglitazone, or proglitazone.
5. Pharmaceutical dosage form, as recited in Claim 1, wherein said diffusion-limiting sleeve material comprises at least one of ethylcellulose and polymethacrylate (Eudragit RS).
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6. Pharmaceutical dosage form, as recited in Claim 5, further comprising a plasticizer.
7. Pharmaceutical dosage form, as recited in Claim 6, wherein said plasticizer comprises at least one of triethylcitrate, dibutylsebacate, glycerin, and tributylcitrate.
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8. Pharmaceutical dosage form, as recited in Claim 1, wherein said core further comprises a matrix material.

9. Pharmaceutical dosage form, as recited in Claim 8, wherein said matrix material comprises at least one material selected from the group consisting of polyethylene glycol, polyvinylalcohol, polymethacrylate, cellulose acetate phthalate, polyvinylpyrrolidone, hydroxypropylcellulose phthalate, hydroxypropylmethylcellulose, hydroxypropylmethylcellulose acetate succinate, hydroxypropylcellulose, hydroxypropylcellulose, and polysorbate 80.

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10. Pharmaceutical dosage form, as recited in Claim 9, wherein said matrix material comprises polyvinylpyrrolidone and polyethylene glycol.

10 11. Pharmaceutical dosage form, as recited in Claim 10, wherein said polyethylene glycol comprises polyethylene glycol having a molecular weight ranging from 400 to 8000.

12. Pharmaceutical dosage form, as recited in Claim 1, wherein said opposite surfaces are planar and are parallel to each other.

15 13. Pharmaceutical dosage form, as recited in Claim 1, wherein said pharmaceutical agent comprises troglitazone and wherein said core further comprises a matrix material comprising polyvinylpyrrolidone and polyethylene glycol 400.

14. Pharmaceutical dosage form, as recited in Claim 13, wherein said diffusion-limiting sleeve material comprises a material selected from the group consisting of at least one of ethylcellulose and polymethacrylate.

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15. Pharmaceutical dosage form, as recited in Claim 14, further comprising a plasticizer.

16. Pharmaceutical dosage form, as recited in Claim 15, wherein said plasticizer comprises at least one of triethylcitrate, dibutylsebacate, glycerine, and tributylcitrate.

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5            17. Method of making a pharmaceutical dosage form comprising coextruding an indefinite length of a central core including a pharmaceutical agent disposed in a controlled-release composition, surrounded by a diffusion-limiting composition, and slicing said co-extrudate across the longitudinal axis thereof.

10            18. Method of making a pharmaceutical dosage form, as recited in Claim 17, wherein said co-extrudate is permitted to harden before said co-extrudate is sliced across the longitudinal axis thereof.

15            19. Method of making a pharmaceutical dosage form, as recited in Claim 17, wherein said co-extrudate is sliced across the longitudinal axis thereof in parallel, perpendicular to said longitudinal axis.

20            20. Method of making a pharmaceutical dosage form, as recited in Claim 17, wherein said co-extrudate is heated to a temperature in the range of 30°C to 250°C.

25            21. Method of making a pharmaceutical dosage form, as recited in Claim 20, wherein said co-extrudate is heated to a temperature in the range of 40°C to 200°C.

30            22. Pharmaceutical dosage form, as recited in Claim 1, wherein said composition is introduced into a capsule.

35            23. Method of making a pharmaceutical dosage form, as recited in Claim 19, wherein said co-extrudate is sliced with a laser across the longitudinal axis of the co-extrudate in parallel, perpendicular to said longitudinal axis.

40            24. Pharmaceutical dosage form, as recited in Claim 1, wherein the core of said composition is released by erosion.